ORIGINAL

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

LASANDRA MADDEN AND LEVELL MADDEN, Individually, and on Behalf of LABREA WILLIAMS, a minor child,	§	
Plaintiffs,	§	CIVIL ACTION No. 3:03-CV-0167-R (BD)
v.	§	
WYETH, d/b/a WYETH, INC., f/k/a AMERICAN HOME PRODUCTS CORPORATION; WYETH CONSUMER HEALTHCARE, AN UNINCORPORATED DIVISION OF WYETH, f/k/a WHITEHALL-ROBINS HEALTHCARE; &WHITEHALL LABORATORIES, INC.,	§	
Defendants.	§	

PLAINTIFFS' MOTION AND BRIEF TO COMPEL DISCOVERY FROM DEFENDANT WYETH

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW La Sandra Madden and Levell Madden, Individually, and on Behalf of Labrea Williams, a minor child, plaintiffs in the above numbered and styled cause, and file this their Motion and Brief to Compel Discovery from Defendant Wyeth, and in support thereof would respectfully show the Court as follows:

I.
Preliminary Statement

Plaintiffs served their First Set of Interrogatories and First Request for Production to defendants (hereinafter collectively "Wyeth") on or about March 25, 2003. On or about May 12, 2003, Wyeth served plaintiffs with its Answers to Plaintiffs' First Request for Production and

Plaintiffs' First Set of Interrogatories[1], which are attached as **Exhibits 1 & 2.**

Wyeth has filed numerous objections to this discovery, some of which are frivolous, without merit and made for the purposes of delay, or has answered incompletely. Additionally, it is now asserting numerous objections that were asserted for the first time almost three months after its initial responses were filed in June, 2003. Further, it has only supplemented with a handful of documents since first answering this discovery, which has been approximately five months ago.

As such, all objections asserted in an untimely manner are waived, and defendant Wyeth should be compelled to completely answer this discovery within ten (10)days from the date of the hearing on this motion. The parties have conferred extensively about these issues over a period of several months, and their **Joint Status Report,** signed by all counsel, is filed herewith.

II.
Discovery in General

In general, "parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter." Fed. R. Civ. P. 26(b)(1).

Discoverable information need not be admissible at trial if the discovery appears "reasonably calculated to lead to the discovery of admissible evidence." *Coughlin v. Lee,* 946 F.2d 1152, 1159 (5th Cir. 1991). The Supreme Court interprets relevancy in the discovery

[1] Based on a computer error with regard to the numbering of the interrogatories, plaintiffs re-served defendants with Plaintiffs' Interrogatories to Defendants–First Set (Revised) which were substituted by agreement for Plaintiffs' Interrogatories to Defendants–First Set. Defendants re-answered such interrogatories on June 10, 2003, to comply with the revised numbering, and such objections and answers are attached hereto as **Exhibit 1.**

context "broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351, 98 S. Ct. 2380, 2389, 57 L. Ed. 2d 253 (1978) (citations omitted).

Discovery that is not "reasonably calculated to lead to the discovery of admissible evidence," however, falls outside the scope of Rule 26. *Id.* at 351-52, 98 S. Ct. at 2390. A party claiming that requested discovery is not relevant has the burden to show that the discovery is outside the scope of the rules. *City of Wichita v. Aero Holdings, Inc.,* 192 F.R.D. 300, 302 (D. Kan. 2000) (emphasis added).

III.
Motion to Compel Discovery from Defendant Wyeth

A. For the reasons stated in the Joint Status Report, filed and served herewith, defendant Wyeth's objections should be overruled and plaintiffs' motion granted.

1) **Specific Interrogatories and Requests For Production**

Interrogatory No. 7 & Request No. 24: Sales information in electronic format.

Interrogatory No. 13 & Request No. 21: Detailed information about all advertising about the drug in question.

Interrogatory No. 14 & Request No. 18: Detailed information about all warnings, instructions, labels or package inserts ever distributed with the drug.

Interrogatory no. 18 & Req. Nos. 5, 6, 7, 8, 9, 10, 12, 15, & 16: Detailed information about all complaints of injury by the drug, and copies of all pre- or post-marketing Adverse Drug Experience Reports (ADEs), either during clinical trials or during the post-marketing period.

Req. Nos. 3 &4; and 13 & 14: All NDA (New Drug Applications).

Req. No. 6: Backup documentation for all ADEs.

Request Nos. 8 & 9: All clinical trials /post-marketing trials from Boston Fever Study and CAMP Study.

Request No. 10: All ADE reports from Boston Fever and CAMP Studies.

Request Nos. 11 & 12: All data in electronic or paper format regarding renal problems in children in the Boston Fever and CAMP Studies

Request Nos. 15 and 16: All post-marketing ADE reports.

Request No. 19: All warning labels on adult Advil.

Request No. 20: All drug defect, customer complaint, or adverse drug experience data bases.

Request No. 21: All advertising, foreign and domestic.

Request No. 22: Unpublished manuscripts.

Request No. 24: Sales data bases in electronic form.

Request No. 26: Lawsuit information about all ibuprofen drugs, including adult Advil.

Request No. 30: FDA inquiries and responses.

Request No. 31: Foreign ADEs from foreign clinical trials.

For discussion, see the Joint Status Report, filed and served herewith.

2) Generic disputes (including some of the above)

A) **Whether Wyeth's GSSE, S3, WATSIN, and sales information electronic databases should be identified and produced in their entirety and in electronic format.** (Interrogatory Nos. 5, 6, 7, and 18, and Request for Production Nos. 3, 5, 7, 9, 11, 13, 14, 15, 20, 24 and 34).

B) **Whether Wyeth should produce worldwide/international documents.** [Interrogatory 13 and Request for Production No 21: (worldwide/international advertising); Interrogatory 14 and Request 18 (detailed information about worldwide/international warnings, labels, etc); Interrogatory 15 and Request 21 (detailed information about worldwide/international brochures and pamphlets); and Request No. 31 (foreign ADEs from foreign clinical trials).].

C) **Lawsuits/notices of claims/labels pertaining to adult Advil (ibuprofen).** (Interrogatory No. 19 and Request for Production Nos. 19 & 26).

D) **Whether defendants are entitled to assert an objection/limitation on documents produced to those adverse events or injuries allegedly suffered by LaBrea Williams, or whether such objection has been waived:** (Interrogatory no. 18 & Req. Nos. 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, & 31: Requesting detailed information about all complaints of injury by the drug, and copies of all pre- or post-marketing Adverse Drug Experience Reports (ADEs), either during clinical trials or during the post-marketing period.).

For discussion, see the Joint Status Report, filed herewith.

IV.
Issues Not Fully Briefed in Joint Status Report

1. **Production of software: Plaintiffs request that Wyeth provide electronic information in a readable, searchable and usable format that will enable plaintiffs' counsel and their experts the ability to adequately utilize the information.**

Plaintiffs seek not only the databases discussed in the Joint Status Report in electronic form, but also the identity of the format of the databases by which the data are inputted and how they can be searched, as well as how the data is saved and backed up. Wyeth, however, has objected to producing software and accompanying manuals claiming that it is a violation of any licensing agreement between Wyeth and the manufacturer of such software. However, Wyeth has made no showing that to disclose such software subject to court order would be a violation of such agreements. Additionally, plaintiffs have agreed to a Protective Order which will protect any such interest of Wyeth.

Because Wyeth maintains the information sought in machine-readable format, it is necessary the plaintiffs be provided the software and manuals to retrieve such information. *See Sattar v. Motorola, Inc.,* 138 F.3d 1164, 1171 (7th Cir. 1998) (defendant produced the equivalent of 210,000 pages on computer tapes but plaintiff lacked the equipment and software to read them; the court ordered the defendant to choose between downloading the data to

conventional computer disks or loaning the plaintiff a copy of the necessary software or offering plaintiff onsite access to its own system); *see also Anderson v. Cornejo,* 2001 WL 219639 (N.D. Ill. 2001) (plaintiff was permitted production of computer database and computer readable format concerning customs activity for statistical analysis); *Crown Life Ins. Co. v. Craig,* 995 F.2d 1376, 1383 (7th Cir. 1993) (Rule 34 contemplates party must make data available in accessible form).

2. Additional arguments regarding specific discovery requests.

A. New Drug Applications, Clinical Trials Data, and ADE data.

Request Nos. 3 &4; 13 & 14: The New Drug Application(s) for prescription (and OTC) Children's Advil in electronic (or alternatively) paper form, *if and only if not available in electronic format.*

Answer: Wyeth will produce documents responsive to (these requests) at a mutually agreeable time and place, subject to an appropriate protective order.

Request No. 5: All clinical trial data for Children's or Pediatric Advil in electronic form done by you or anyone either before or after the drug was first approved for over-the-counter (OTC) distribution by you, together with the software used to access it and the user manuals for said software.

Answer: Wyeth does not have in its possession documents in electronic format responsive to this request. Documents in paper format . . are contained in the New Drug Applications . . . (which) will be made available for inspection and copying at a mutually agreeable time and place, subject to an appropriate protective order.

Request No. 6: All adverse drug experience reports (ADE's) in paper form, with all accompanying backup documents, for all ADE's associated with the drug during all clinical trials, both pre and post OTC distribution.

Answer: Any documents in Wyeth's possession responsive to this request are contained in the NDAs for Children's Advil . . . .

Request No. 10: All paper ADE reports from the Boston Fever Study or the CAMP study reporting any of the ADE's listed in Request no. 9, above.

Answer: Any documents in Wyeth's possession responsive to this request are contained in the NDA's for Children's Advil. The NDAs will made available for inspection and copying at a mutually agreeable time and place, subject to an appropriate protective order.

Request No. 11: All data in electronic format showing the number of renal problems of any kind in children included in the Boston Fever Study and/or the CAMP Study; together with the software used to access it and the user manuals for said software.

Answer: Wyeth objects to this request as irrelevant and not seeking documents reasonably calculated . . . Wyeth further objects to the extent it requires Wyeth to produce software . . . Subject to and without waiving the foregoing objections, Wyeth will produce documents responsive to this request. Subject to and without waiver of the foregoing objections, Wyeth does not have in its possession any documents responsive to this request.

Request Nos. 15: All post-marketing ADE reports received by you from the time you first began distributing this drug either by prescription or OTC, in electronic and paper format, together with the software used to access this data . . .

Answer: Wyeth objects to this request as irrelevant . . . Wyeth further objects to the extent it requires Wyeth to produce software . . . Subject to and without waiving the foregoing objection, Wyeth does not have in its possession documents in electronic format responsive to this request . . . Wyeth will also produce responsive information in electronic format.

Request No. 16: All underlying paper documentation of said ADE reports referred to in request 15 above, including reports by physicians, pharmacists, hospital personnel, or detail persons regarding the diagnoses listed in request no. 9 above, or dealing with renal problems of any kind.

Answer: Any documents in Wyeth's possession responsive . . . are contained in the NDAs for Children's Advil . . .

The complete New Drug Application(s), all clinical trials information, and all pre- and post-marketing ADE data are fundamental in any drug product liability case, and initially Wyeth agreed to produce most of it, by tendering the New Drug Applications in toto, subject to a proposed Protective Order, which has now been agreed to. Now, some four months after their initial responses were filed, long after such objections have been waived, they are attempting to limit their production to "skin-related adverse events". This objection has been waived, and for the reasons shown in the Joint Status Report, production of these documents should be fully and

completely compelled. **(See, Discussion and arguments in Joint Status Report).**

Additionally, they are refusing to produce all post-marketing ADE data, choosing belatedly to limit such production to skin-related adverse events. Additionally, there exist documents that will not be contained in the NDA that are responsive to these requests, which are maintained by the defendant in the Wyeth Global Safety Surveillance and Epidemiology Department Adverse Event Data Collection and Safety Reporting System, such as Forms 1747A & B-Adverse Event Records; Request for Safety Query Forms; Periodic Safety Update Reports (PSURS) GSSE2 safety queries. **(See, Att. 5, Joint Status Report).**

Additionally, plaintiffs are seeking "source documents," which are medical records, statements, or follow-up reports which are separate documents gathered by the defendants to investigate adverse events, and are necessary to prove causality of the adverse event to the drug. Plaintiffs seek confirmation that such documents will be provided at time of inspection of the NDA.

IV.

WHEREFORE, PREMISES CONSIDERED, plaintiffs respectfully request that upon hearing of this matter, and based on their arguments outline in the Joint Status Report, filed herewith, the Court would overrule each of the defendant's objections to the requested discovery and order it to produce this discovery within ten (10) days of the date of this hearing, grant plaintiffs reasonable attorney's fees on this motion, and grant all such other and further relief to which plaintiffs may be justly entitled.

Dated the 12 ~~day of~~ November, 2003.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF CONFERENCE

Counsel for movant , JAMES C. BARBER, has conferred extensively with defense counsel, as shown in the accompanying Joint Status Report filed herewith, and there are numerous fundamental differences remaining between the parties, as set out in the above motion and the Joint Status Report. The reasons the parties could not reach agreement are set out in detail in the Joint Status Report.

Certified to the 12 day of November, 2003, by: _____.
JAMES C. BARBER

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of this document has been served, via fax and certified mail, return receipt requested, to all counsel of record, on this the _____ day of ~~August~~ November, 2003.

_____
JAMES C. BARBER

FIAT

The above and foregoing Motion is set for hearing on the _____ day of _____, 2003, at _____ o'clock _____. m.

_____

JUDGE PRESIDING